IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AUXILIUM PHARMACEUTICALS, INC. and FCB I, LLC,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
UPSHER-SMITH LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Auxilium Pharmaceuticals, Inc. and FCB I, LLC Pharmaceuticals, Inc. (collectively, "Plaintiffs"), by their attorneys, for their complaint against Defendant Upsher-Smith Laboratories, Inc. ("Upsher-Smith") hereby allege as follows:

THE PARTIES

1. Auxilium Pharmaceuticals, Inc. ("Auxilium") is a Delaware corporation with its principal place of business at 40 Valley Stream Parkway, Malvern, Pennsylvania, 19355. Auxilium is in the business of developing and marketing pharmaceutical products.

2. FCB I, LLC ("FCB") is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 1105 North Market Street, Suite 1300, Wilmington, Delaware 19801.

3. Upon information and belief, Upsher-Smith Laboratories, Inc. ("Upsher-Smith") is a company organized and existing under the laws of Minnesota with a principal place of business at 6701 Evenstad Drive, Maple Grove, Minnesota, 55369. Upon information and belief, Defendant Upsher-Smith manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

4. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the U.S. Code, for infringement of U.S. Patent Nos. 7,320,968 (the "'968 Patent"); 7,608,605 (the "'605 Patent"); 7,608,606 (the "'606 Patent"); 7,608,607 (the "'607 Patent"); 7,608,608 (the "'608 Patent"); 7,608,609 (the "'609 Patent"); 7,608,610 (the "'610 Patent"); 7,935,690 (the "'690 Patent"); 8,063,029 (the "'029 Patent"); and 8,178,518 (the "'518 Patent") (collectively, "the Patents-in-Suit"). This action relates to a New Drug Application ("NDA") filed by Upsher-Smith with FDA pursuant to 21 U.S.C. § 355(b)(2), seeking approval to market a version of Auxilium's highly successful Testim®.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Upsher-Smith by virtue of the fact that, *inter alia*, Upsher-Smith has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Auxilium and FCB. Upon information and belief, this Court has personal jurisdiction over Upsher-Smith for the additional reasons set forth below and for other reasons that will be presented to the Court, if such jurisdiction is challenged.

7. Upon information and belief, this Court has personal jurisdiction over Upsher-Smith by virtue of, *inter alia*, its systematic and continuous contacts with Delaware. Upsher-Smith manufactures numerous drugs for sale and use throughout the United States, including this judicial district, and derives substantial revenue from the State of Delaware through the sale and consumption of its pharmaceutical products. Upon information and belief, Upsher-Smith is

registered in Delaware as a manufacturer of drugs, Registration No. DS0470, and as a wholesaler of drugs, Registration No. A4-0001180.

8. Upsher-Smith has previously submitted itself to the jurisdiction of the U.S. District Court for the District of Delaware. *See, e.g., Auxilium Pharms., Inc. et al. v. Upsher-Smith Laboratories, Inc*., No. 08-cv-00908-SLR (D. Del.). In the same case, it purposefully availed itself of the jurisdiction of this Court by asserting counterclaims. *Id.* (D.I. Nos. 6 and 36).

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b).

BACKGROUND

The Patents-In-Suit

10. The ’968 Patent, entitled “Pharmaceutical Composition,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on January 22, 2008. The term of the ’968 Patent expires in January 2025. A true and correct copy of the ’968 Patent is attached as Exhibit A.

11. In May 2000, Auxilium and FCB’s predecessor-in-interest, Bentley Pharmaceuticals, Inc. (“Bentley”), entered into a License Agreement (“License Agreement”) whereby, *inter alia*, Auxilium was granted (a) an exclusive world-wide license to U.S. Serial No. 10/473,724 (which issued as the ’968 Patent) and to any and all continuations, continuations-in-part, additions, divisions, renewals, extensions, re-examinations and reissues thereof, including any and all foreign counterparts; and (b) the right to sue for infringement of the ’968 Patent.

12. In 2008, CPEX Pharmaceuticals, Inc. ("CPEX") was spun out of Bentley and CPEX became the owner of the '968 Patent and related patent applications, as well as the licensor under the aforementioned License Agreement.

13. In 2011, CPEX assigned all rights to the '968 Patent to FCB, including its rights in the aforementioned License Agreement.

14. FCB is the lawful owner by assignment of the '968 Patent and has the right to sue for infringement of the '968 Patent. Auxilium is the exclusive licensee of the '968 Patent.

15. The '605 Patent, entitled "Pharmaceutical Composition," was duly and legally issued by the USPTO on October 27, 2009. Application No. 12/356,513 (which issued as the '605 Patent) is a continuation of Application No. 10/473,724 (which issued as the '968 Patent). A true and correct copy of the '605 Patent is attached as Exhibit B.

16. FCB is the lawful owner by assignment of the '605 Patent and has the right to sue for infringement of the '605 Patent. Auxilium is the exclusive licensee of the '605 Patent.

17. The '606 Patent, entitled "Pharmaceutical Composition," was duly and legally issued by the USPTO on October 27, 2009. Application No. 12/356,515 (which issued as the '606 Patent) is a continuation of Application No. 10/473,724 (which issued as the '968 Patent). A true and correct copy of the '606 Patent is attached as Exhibit C.

18. FCB is the lawful owner by assignment of the '606 Patent and has the right to sue for infringement of the '606 Patent. Auxilium is the exclusive licensee of the '606 Patent.

19. The '607 Patent, entitled "Pharmaceutical Composition," was duly and legally issued by the USPTO on October 27, 2009. Application No. 12/356,943 (which issued as the '607 Patent) is a continuation of Application No. 10/473,724 (which issued as the '968 Patent). A true and correct copy of the '607 Patent is attached as Exhibit D.

20. FCB is the lawful owner by assignment of the ’607 Patent and has the right to sue for infringement of the ’607 Patent. Auxilium is the exclusive licensee of the ’607 Patent.

21. The ’608 Patent, entitled “Pharmaceutical Composition,” was duly and legally issued by the USPTO on October 27, 2009. Application No. 12/359,162 (which issued as the ’608 Patent) is a continuation of Application No. 10/473,724 (which issued as the ’968 Patent). A true and correct copy of the ’608 Patent is attached as Exhibit E.

22. FCB is the lawful owner by assignment of the ’608 Patent and has the right to sue for infringement of the ’608 Patent. Auxilium is the exclusive licensee of the ’608 Patent.

23. The ’609 Patent, entitled “Pharmaceutical Composition,” was duly and legally issued by the USPTO on October 27, 2009. Application No. 12/359,183 (which issued as the ’609 Patent) is a continuation of Application No. 10/473,724 (which issued as the ’968 Patent). A true and correct copy of the ’609 Patent is attached as Exhibit F.

24. FCB is the lawful owner by assignment of the ’609 Patent and has the right to sue for infringement of the ’609 Patent. Auxilium is the exclusive licensee of the ’609 Patent.

25. The ’610 Patent, entitled “Pharmaceutical Composition,” was duly and legally issued by the USPTO on October 27, 2009. Application No. 12/364,413 (which issued as the ’610 Patent) is a continuation of Application No. 10/473,724 (which issued as the ’968 Patent). A true and correct copy of the ’610 Patent is attached as Exhibit G.

26. FCB is the lawful owner by assignment of the ’610 Patent and has the right to sue for infringement of the ’610 Patent. Auxilium is the exclusive licensee of the ’610 Patent.

27. The ’690 Patent, entitled “Pharmaceutical Composition,” was duly and legally issued by the USPTO on May 3, 2011. Application No. 11/928,467 (which issued as the

’690 Patent) is a continuation of Application No. 10/473,724 (which issued as the ’968 Patent). A true and correct copy of the ’690 Patent is attached as Exhibit H.

28. FCB is the lawful owner by assignment of the ’690 Patent and has the right to sue for infringement of the ’690 Patent. Auxilium is the exclusive licensee of the ’690 Patent.

29. The ’029 Patent, entitled “Pharmaceutical Composition,” was duly and legally issued by the USPTO on November 22, 2011. Application No. 11/930,812 (which issued as the ’029 Patent) is a continuation of Application No. 10/473,724 (which issued as the ’968 Patent). A true and correct copy of the ’029 Patent is attached as Exhibit I.

30. FCB is the lawful owner by assignment of the ’029 Patent and has the right to sue for infringement of the ’029 Patent. Auxilium is the exclusive licensee of the ’029 Patent.

31. The ’518 Patent, entitled “Pharmaceutical Composition,” was duly and legally issued by the USPTO on May 15, 2012. Application No. 11/931,809 (which issued as the ’518 Patent) is a continuation of Application No. 10/473,724 (which issued as the ’968 Patent). A true and correct copy of the ’518 Patent is attached as Exhibit J.

32. FCB is the lawful owner by assignment of the ’518 Patent and has the right to sue for infringement of the ’518 Patent. Auxilium is the exclusive licensee of the ’518 Patent.

Development of the Approved Drug Product

33. Auxilium is the holder of approved New Drug Application (“NDA”) 21-454 for a transdermal testosterone gel, which has the proprietary name Testim® and is sold by Auxilium throughout the United States. Testim® has been approved by the United States Food and Drug Administration (“FDA”) for the treatment of hypogonadism in men, which is a medical condition that occurs when the body does not make enough testosterone.

34. Auxilium has listed the ’968 Patent; the ’605 Patent; the ’606 Patent; the ’607 Patent; the ’608 Patent; the ’609 Patent; the ’610 Patent; the ’690 Patent; the ’029 Patent; and the ’518 Patent in the Orange Book—formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*— in connection with NDA No. 21-454.

USL’s Previous ANDA for Testim®

35. Prior to October 22, 2008, Upsher-Smith filed with FDA Abbreviated New Drug Application 79-178 (“the Upsher-Smith ANDA”) with, among other things, a paragraph IV certification to the ’968 Patent under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for a 1% testosterone transdermal gel product purportedly bioequivalent to Testim®. The purpose of the ANDA was to obtain FDA approval for the commercial manufacture, use, and sale of a generic Testim® product.

36. On behalf of Upsher-Smith, Sean B. Mahoney, counsel for Upsher-Smith, sent a letter dated October 22, 2008, to Auxilium and Bentley, to provide notice, pursuant to 21 U.S.C. § 355(j)(2)(B), that Upsher-Smith had filed the Upsher-Smith ANDA with respect to testosterone transdermal gel in a 1% strength. The notice letter represented that Upsher-Smith had submitted to FDA the Upsher-Smith ANDA with a paragraph IV certification to the ’968 Patent.

37. In response to the October 22, 2008 letter, Auxilium and FCB’s predecessor-in-interest, CPEX, brought a Hatch-Waxman suit for patent infringement in this Court, in a case captioned *Auxilium Pharmaceuticals, Inc. et al. v. Upsher-Smith Laboratories, Inc*., No. 08-cv-00908-SLR (D. Del., filed Dec. 4, 2008).

38. Upsher-Smith has not received FDA approval of the Upsher-Smith ANDA.

39. The patent infringement suit captioned *Auxilium Pharmaceuticals, Inc. et al. v. Upsher-Smith Laboratories, Inc*., No. 08-cv-00908-SLR (D. Del.), is still pending in this Court, but has been administratively closed since December 2011.

Upsher-Smith's NDA

40. Now, upon information and belief, Upsher-Smith has filed New Drug Application ("NDA") 204399 with FDA under section 21 U.S.C. § 355(b)(2), with paragraph IV certifications to the Patents-in-Suit to obtain FDA approval for the commercial manufacture, use, and sale of a testosterone transdermal gel product in a 1% strength which it alleges is "qualitatively and quantitatively the same formulation that is the subject of [Upsher-Smith ANDA]." Upon information and belief, Upsher-Smith filed NDA 204399 with paragraph IV certifications, to obtain approval to market a version of Auxilium's Testim® before the expiration of the Patents-in-Suit.

41. On behalf of Upsher-Smith, Sean B. Mahoney, counsel for Upsher-Smith, sent a letter dated December 21, 2012, to Auxilium and FCB, to provide notice, pursuant to 21 U.S.C. § 355(b)(3), that Upsher-Smith had filed NDA 204399 with respect to testosterone transdermal gel in a 1% strength. The notice letter represented that Upsher-Smith had submitted to FDA NDA 204399 with paragraph IV certifications to the '968 Patent, the '605 Patent, the '606 Patent, the '607 Patent, the '608 Patent, the '609 Patent, the '610 Patent, the '690 Patent, the '029 Patent, and the '518 Patent.

COUNT I - INFRINGEMENT OF THE '968 PATENT

42. The allegations of the preceding paragraphs 1–41 are repeated, realleged, and incorporated herein by reference.

43. Upon information and belief, Upsher-Smith's Paragraph IV certification alleged that its testosterone transdermal gel product in NDA 204399 will not infringe any claims of the '968 Patent, and/or that the '968 Patent is invalid or unenforceable.

44. Under 35 U.S.C. § 271(e)(2)(A), Upsher-Smith's submission to FDA of NDA 204399 to obtain approval for the commercial manufacture, use, or sale of its testosterone transdermal gel product before the expiration of the '968 Patent constitutes infringement of the '968 Patent.

45. Upon FDA approval of NDA 204399 and upon information and belief, Upsher-Smith will infringe the '968 Patent by making, using, offering to sell, selling, and/or importing the testosterone transdermal gel product in the United States, and/or by actively inducing and/or by contributing to infringement by others under 35 U.S.C. § 271, unless this Court orders that the effective date of any FDA approval of Upsher-Smith's NDA shall be no earlier than the expiration date of the '968 Patent.

46. Upon information and belief, Upsher-Smith's testosterone transdermal gel product in NDA 204399 constitutes a material part of at least one of the claims of the '968 Patent; Upsher-Smith knows that its testosterone transdermal gel product is especially made or adapted for use in a manner infringing at least one of the claims of the '968 Patent; and Upsher-Smith's testosterone transdermal gel product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

47. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith's testosterone transdermal gel product in NDA 204399 would contributorily infringe at least one of the claims of the '968 Patent.

48. Upon information and belief, Upsher-Smith had knowledge of the ’968 Patent and, by its promotional activities and package insert for its testosterone transdermal gel product in NDA 204399, Upsher-Smith knows or should know that it will actively aid and abet another’s infringement of at least one of the claims of the ’968 Patent.

49. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith’s testosterone transdermal gel product in NDA 204399 would actively induce infringement of at least one of the claims of the ’968 Patent.

50. Auxilium and FCB will be substantially and irreparably harmed by Upsher-Smith’s infringing activities unless those activities are enjoined by this Court. Auxilium and FCB have no adequate remedy at law.

COUNT II - INFRINGEMENT OF THE ’605 PATENT

51. The allegations of the preceding paragraphs 1–50 are repeated, realleged, and incorporated herein by reference.

52. Upon information and belief, Upsher-Smith’s Paragraph IV certification alleged that its testosterone transdermal gel product in NDA 204399 will not infringe any claims of the ’605 Patent, and/or that the ’605 Patent is invalid or unenforceable.

53. Under 35 U.S.C. § 271(e)(2)(A), Upsher-Smith’s submission to FDA of NDA 204399 to obtain approval for the commercial manufacture, use, or sale of its testosterone transdermal gel product before the expiration of the ’605 Patent constitutes infringement of the ’605 Patent.

54. Upon FDA approval of NDA 204399 and upon information and belief, Upsher-Smith will infringe the ’605 Patent by making, using, offering to sell, selling, and/or importing the testosterone transdermal gel product in the United States, and/or by actively inducing and/or

by contributing to infringement by others under 35 U.S.C. § 271, unless this Court orders that the effective date of any FDA approval of Upsher-Smith's NDA shall be no earlier than the expiration date of the '605 Patent.

55. Upon information and belief, Upsher-Smith's testosterone transdermal gel product in NDA 204399 constitutes a material part of at least one of the claims of the '605 Patent; Upsher-Smith knows that its testosterone transdermal gel product is especially made or adapted for use in a manner infringing at least one of the claims of the '605 Patent; and Upsher-Smith's testosterone transdermal gel product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

56. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith's testosterone transdermal gel product in NDA 204399 would contributorily infringe at least one of the claims of the '605 Patent.

57. Upon information and belief, Upsher-Smith had knowledge of the '605 Patent and, by its promotional activities and package insert for its testosterone transdermal gel product in NDA 204399, Upsher-Smith knows or should know that it will actively aid and abet another's infringement of at least one of the claims of the '605 Patent.

58. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith's testosterone transdermal gel product in NDA 204399 would actively induce infringement of at least one of the claims of the '605 Patent.

59. Auxilium and FCB will be substantially and irreparably harmed by Upsher-Smith's infringing activities unless those activities are enjoined by this Court. Auxilium and FCB have no adequate remedy at law.

COUNT III - INFRINGEMENT OF THE ’606 PATENT

60. The allegations of the preceding paragraphs 1–59 are repeated, realleged, and incorporated herein by reference.

61. Upon information and belief, Upsher-Smith’s Paragraph IV certification alleged that its testosterone transdermal gel product in NDA 204399 will not infringe any claims of the ’606 Patent, and/or that the ’606 Patent is invalid or unenforceable.

62. Under 35 U.S.C. § 271(e)(2)(A), Upsher-Smith’s submission to FDA of NDA 204399 to obtain approval for the commercial manufacture, use, or sale of its testosterone transdermal gel product before the expiration of the ’606 Patent constitutes infringement of the ’606 Patent.

63. Upon FDA approval of NDA 204399 and upon information and belief, Upsher-Smith will infringe the ’606 Patent by making, using, offering to sell, selling, and/or importing the testosterone transdermal gel product in the United States, and/or by actively inducing and/or by contributing to infringement by others under 35 U.S.C. § 271, unless this Court orders that the effective date of any FDA approval of Upsher-Smith’s NDA shall be no earlier than the expiration date of the ’606 Patent.

64. Upon information and belief, Upsher-Smith’s testosterone transdermal gel product in NDA 204399 constitutes a material part of at least one of the claims of the ’606 Patent; Upsher-Smith knows that its testosterone transdermal gel product is especially made or adapted for use in a manner infringing at least one of the claims of the ’606 Patent; and Upsher-Smith’s testosterone transdermal gel product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

65. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith's testosterone transdermal gel product in NDA 204399 would contributorily infringe at least one of the claims of the '606 Patent.

66. Upon information and belief, Upsher-Smith had knowledge of the '606 Patent and, by its promotional activities and package insert for its testosterone transdermal gel product in NDA 204399, Upsher-Smith knows or should know that it will actively aid and abet another's infringement of at least one of the claims of the '606 Patent.

67. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith's testosterone transdermal gel product in NDA 204399 would actively induce infringement of at least one of the claims of the '606 Patent.

68. Auxilium and FCB will be substantially and irreparably harmed by Upsher-Smith's infringing activities unless those activities are enjoined by this Court. Auxilium and FCB have no adequate remedy at law.

COUNT IV - INFRINGEMENT OF THE '607 PATENT

69. The allegations of the preceding paragraphs 1–68 are repeated, realleged, and incorporated herein by reference.

70. Upon information and belief, Upsher-Smith's Paragraph IV certification alleged that its testosterone transdermal gel product in NDA 204399 will not infringe any claims of the '607 Patent, and/or that the '607 Patent is invalid or unenforceable.

71. Under 35 U.S.C. § 271(e)(2)(A), Upsher-Smith's submission to FDA of NDA 204399 to obtain approval for the commercial manufacture, use, or sale of its testosterone transdermal gel product before the expiration of the '607 Patent constitutes infringement of the '607 Patent.

72. Upon FDA approval of NDA 204399 and upon information and belief, Upsher-Smith will infringe the ’607 Patent by making, using, offering to sell, selling, and/or importing the testosterone transdermal gel product in the United States, and/or by actively inducing and/or by contributing to infringement by others under 35 U.S.C. § 271, unless this Court orders that the effective date of any FDA approval of Upsher-Smith’s NDA shall be no earlier than the expiration date of the ’607 Patent.

73. Upon information and belief, Upsher-Smith’s testosterone transdermal gel product in NDA 204399 constitutes a material part of at least one of the claims of the ’607 Patent; Upsher-Smith knows that its testosterone transdermal gel product is especially made or adapted for use in a manner infringing at least one of the claims of the ’607 Patent; and Upsher-Smith’s testosterone transdermal gel product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

74. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith’s testosterone transdermal gel product in NDA 204399 would contributorily infringe at least one of the claims of the ’607 Patent.

75. Upon information and belief, Upsher-Smith had knowledge of the ’607 Patent and, by its promotional activities and package insert for its testosterone transdermal gel product in NDA 204399, Upsher-Smith knows or should know that it will actively aid and abet another’s infringement of at least one of the claims of the ’607 Patent.

76. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith’s testosterone transdermal gel product in NDA 204399 would actively induce infringement of at least one of the claims of the ’607 Patent.

77. Auxilium and FCB will be substantially and irreparably harmed by Upsher-Smith's infringing activities unless those activities are enjoined by this Court. Auxilium and FCB have no adequate remedy at law.

COUNT V - INFRINGEMENT OF THE '608 PATENT

78. The allegations of the preceding paragraphs 1–77 are repeated, realleged, and incorporated herein by reference.

79. Upon information and belief, Upsher-Smith's Paragraph IV certification alleged that its testosterone transdermal gel product in NDA 204399 will not infringe any claims of the '608 Patent, and/or that the '608 Patent is invalid or unenforceable.

80. Under 35 U.S.C. § 271(e)(2)(A), Upsher-Smith's submission to FDA of NDA 204399 to obtain approval for the commercial manufacture, use, or sale of its testosterone transdermal gel product before the expiration of the '608 Patent constitutes infringement of the '608 Patent.

81. Upon FDA approval of NDA 204399 and upon information and belief, Upsher-Smith will infringe the '608 Patent by making, using, offering to sell, selling, and/or importing the testosterone transdermal gel product in the United States, and/or by actively inducing and/or by contributing to infringement by others under 35 U.S.C. § 271, unless this Court orders that the effective date of any FDA approval of Upsher-Smith's NDA shall be no earlier than the expiration date of the '608 Patent.

82. Upon information and belief, Upsher-Smith's testosterone transdermal gel product in NDA 204399 constitutes a material part of at least one of the claims of the '608 Patent; Upsher-Smith knows that its testosterone transdermal gel product is especially made or adapted for use in a manner infringing at least one of the claims of the '608 Patent; and Upsher-

Smith's testosterone transdermal gel product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

83. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith's testosterone transdermal gel product in NDA 204399 would contributorily infringe at least one of the claims of the '608 Patent.

84. Upon information and belief, Upsher-Smith had knowledge of the '608 Patent and, by its promotional activities and package insert for its testosterone transdermal gel product in NDA 204399, Upsher-Smith knows or should know that it will actively aid and abet another's infringement of at least one of the claims of the '608 Patent.

85. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith's testosterone transdermal gel product in NDA 204399 would actively induce infringement of at least one of the claims of the '608 Patent.

86. Auxilium and FCB will be substantially and irreparably harmed by Upsher-Smith's infringing activities unless those activities are enjoined by this Court. Auxilium and FCB have no adequate remedy at law.

COUNT VI - INFRINGEMENT OF THE '609 PATENT

87. The allegations of the preceding paragraphs 1–86 are repeated, realleged, and incorporated herein by reference.

88. Upon information and belief, Upsher-Smith's Paragraph IV certification alleged that its testosterone transdermal gel product in NDA 204399 will not infringe any claims of the '609 Patent, and/or that the '609 Patent is invalid or unenforceable.

89. Under 35 U.S.C. § 271(e)(2)(A), Upsher-Smith's submission to FDA of NDA 204399 to obtain approval for the commercial manufacture, use, or sale of its testosterone

transdermal gel product before the expiration of the ’609 Patent constitutes infringement of the ’609 Patent.

90. Upon FDA approval of NDA 204399 and upon information and belief, Upsher-Smith will infringe the ’609 Patent by making, using, offering to sell, selling, and/or importing the testosterone transdermal gel product in the United States, and/or by actively inducing and/or by contributing to infringement by others under 35 U.S.C. § 271, unless this Court orders that the effective date of any FDA approval of Upsher-Smith’s NDA shall be no earlier than the expiration date of the ’609 Patent.

91. Upon information and belief, Upsher-Smith’s testosterone transdermal gel product in NDA 204399 constitutes a material part of at least one of the claims of the ’609 Patent; Upsher-Smith knows that its testosterone transdermal gel product is especially made or adapted for use in a manner infringing at least one of the claims of the ’609 Patent; and Upsher-Smith’s testosterone transdermal gel product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

92. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith’s testosterone transdermal gel product in NDA 204399 would contributorily infringe at least one of the claims of the ’609 Patent.

93. Upon information and belief, Upsher-Smith had knowledge of the ’609 Patent and, by its promotional activities and package insert for its testosterone transdermal gel product in NDA 204399, Upsher-Smith knows or should know that it will actively aid and abet another’s infringement of at least one of the claims of the ’609 Patent.

94. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith's testosterone transdermal gel product in NDA 204399 would actively induce infringement of at least one of the claims of the '609 Patent.

95. Auxilium and FCB will be substantially and irreparably harmed by Upsher-Smith's infringing activities unless those activities are enjoined by this Court. Auxilium and FCB have no adequate remedy at law.

COUNT VII - INFRINGEMENT OF THE '610 PATENT

96. The allegations of the preceding paragraphs 1–95 are repeated, realleged, and incorporated herein by reference.

97. Upon information and belief, Upsher-Smith's Paragraph IV certification alleged that its testosterone transdermal gel product in NDA 204399 will not infringe any claims of the '610 Patent, and/or that the '610 Patent is invalid or unenforceable.

98. Under 35 U.S.C. § 271(e)(2)(A), Upsher-Smith's submission to FDA of NDA 204399 to obtain approval for the commercial manufacture, use, or sale of its testosterone transdermal gel product before the expiration of the '610 Patent constitutes infringement of the '610 Patent.

99. Upon FDA approval of NDA 204399 and upon information and belief, Upsher-Smith will infringe the '610 Patent by making, using, offering to sell, selling, and/or importing the testosterone transdermal gel product in the United States, and/or by actively inducing and/or by contributing to infringement by others under 35 U.S.C. § 271, unless this Court orders that the effective date of any FDA approval of Upsher-Smith's NDA shall be no earlier than the expiration date of the '610 Patent.

100. Upon information and belief, Upsher-Smith's testosterone transdermal gel product in NDA 204399 constitutes a material part of at least one of the claims of the '610

Patent; Upsher-Smith knows that its testosterone transdermal gel product is especially made or adapted for use in a manner infringing at least one of the claims of the ’610 Patent; and Upsher-Smith’s testosterone transdermal gel product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

101. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith’s testosterone transdermal gel product in NDA 204399 would contributorily infringe at least one of the claims of the ’610 Patent.

102. Upon information and belief, Upsher-Smith had knowledge of the ’610 Patent and, by its promotional activities and package insert for its testosterone transdermal gel product in NDA 204399, Upsher-Smith knows or should know that it will actively aid and abet another’s infringement of at least one of the claims of the ’610 Patent.

103. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith’s testosterone transdermal gel product in NDA 204399 would actively induce infringement of at least one of the claims of the ’610 Patent.

104. Auxilium and FCB will be substantially and irreparably harmed by Upsher-Smith’s infringing activities unless those activities are enjoined by this Court. Auxilium and FCB have no adequate remedy at law.

COUNT VIII - INFRINGEMENT OF THE ’690 PATENT

105. The allegations of the preceding paragraphs 1–104 are repeated, realleged, and incorporated herein by reference.

106. Upon information and belief, Upsher-Smith’s Paragraph IV certification alleged that its testosterone transdermal gel product in NDA 204399 will not infringe any claims of the ’690 Patent, and/or that the ’610 Patent is invalid or unenforceable.

107. Under 35 U.S.C. § 271(e)(2)(A), Upsher-Smith's submission to FDA of NDA 204399 to obtain approval for the commercial manufacture, use, or sale of its testosterone transdermal gel product before the expiration of the '690 Patent constitutes infringement of the '690 Patent.

108. Upon FDA approval of NDA 204399 and upon information and belief, Upsher-Smith will infringe the '690 Patent by making, using, offering to sell, selling, and/or importing the testosterone transdermal gel product in the United States, and/or by actively inducing and/or by contributing to infringement by others under 35 U.S.C. § 271, unless this Court orders that the effective date of any FDA approval of Upsher-Smith's NDA shall be no earlier than the expiration date of the '690 Patent.

109. Upon information and belief, Upsher-Smith's testosterone transdermal gel product in NDA 204399 constitutes a material part of at least one of the claims of the '690 Patent; Upsher-Smith knows that its testosterone transdermal gel product is especially made or adapted for use in a manner infringing at least one of the claims of the '690 Patent; and Upsher-Smith's testosterone transdermal gel product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

110. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith's testosterone transdermal gel product in NDA 204399 would contributorily infringe at least one of the claims of the '690 Patent.

111. Upon information and belief, Upsher-Smith had knowledge of the '690 Patent and, by its promotional activities and package insert for its testosterone transdermal gel product in NDA 204399, Upsher-Smith knows or should know that it will actively aid and abet another's infringement of at least one of the claims of the '690 Patent.

112. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith's testosterone transdermal gel product in NDA 204399 would actively induce infringement of at least one of the claims of the '690 Patent.

113. Auxilium and FCB will be substantially and irreparably harmed by Upsher-Smith's infringing activities unless those activities are enjoined by this Court. Auxilium and FCB have no adequate remedy at law.

COUNT IX - INFRINGEMENT OF THE '029 PATENT

114. The allegations of the preceding paragraphs 1–113 are repeated, realleged, and incorporated herein by reference.

115. Upon information and belief, Upsher-Smith's Paragraph IV certification alleged that its testosterone transdermal gel product in NDA 204399 will not infringe any claims of the '029 Patent, and/or that the '029 Patent is invalid or unenforceable.

116. Under 35 U.S.C. § 271(e)(2)(A), Upsher-Smith's submission to FDA of NDA 204399 to obtain approval for the commercial manufacture, use, or sale of its testosterone transdermal gel product before the expiration of the '029 Patent constitutes infringement of the '029 Patent.

117. Upon FDA approval of NDA 204399 and upon information and belief, Upsher-Smith will infringe the '029 Patent by making, using, offering to sell, selling, and/or importing the testosterone transdermal gel product in the United States, and/or by actively inducing and/or by contributing to infringement by others under 35 U.S.C. § 271, unless this Court orders that the effective date of any FDA approval of Upsher-Smith's NDA shall be no earlier than the expiration date of the '029 Patent.

118. Upon information and belief, Upsher-Smith's testosterone transdermal gel product in NDA 204399 constitutes a material part of at least one of the claims of the '029

Patent; Upsher-Smith knows that its testosterone transdermal gel product is especially made or adapted for use in a manner infringing at least one of the claims of the ’029 Patent; and Upsher-Smith’s testosterone transdermal gel product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

119. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith’s testosterone transdermal gel product in NDA 204399 would contributorily infringe at least one of the claims of the ’029 Patent.

120. Upon information and belief, Upsher-Smith had knowledge of the ’029 Patent and, by its promotional activities and package insert for its testosterone transdermal gel product in NDA 204399, Upsher-Smith knows or should know that it will actively aid and abet another’s infringement of at least one of the claims of the ’029 Patent.

121. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith’s testosterone transdermal gel product in NDA 204399 would actively induce infringement of at least one of the claims of the ’029 Patent.

122. Auxilium and FCB will be substantially and irreparably harmed by Upsher-Smith’s infringing activities unless those activities are enjoined by this Court. Auxilium and FCB have no adequate remedy at law.

COUNT X - INFRINGEMENT OF THE ’518 PATENT

123. The allegations of the preceding paragraphs 1–122 are repeated, realleged, and incorporated herein by reference.

124. Upon information and belief, Upsher-Smith’s Paragraph IV certification alleged that its testosterone transdermal gel product in NDA 204399 will not infringe any claims of the ’518 Patent, and/or that the ’518 Patent is invalid or unenforceable.

125. Under 35 U.S.C. § 271(e)(2)(A), Upsher-Smith's submission to FDA of NDA 204399 to obtain approval for the commercial manufacture, use, or sale of its testosterone transdermal gel product before the expiration of the '518 Patent constitutes infringement of the '518 Patent.

126. Upon FDA approval of NDA 204399 and upon information and belief, Upsher-Smith will infringe the '518 Patent by making, using, offering to sell, selling, and/or importing the testosterone transdermal gel product in the United States, and/or by actively inducing and/or by contributing to infringement by others under 35 U.S.C. § 271, unless this Court orders that the effective date of any FDA approval of Upsher-Smith's NDA shall be no earlier than the expiration date of the '518 Patent.

127. Upon information and belief, Upsher-Smith's testosterone transdermal gel product in NDA 204399 constitutes a material part of at least one of the claims of the '518 Patent; Upsher-Smith knows that its testosterone transdermal gel product is especially made or adapted for use in a manner infringing at least one of the claims of the '518 Patent; and Upsher-Smith's testosterone transdermal gel product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

128. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith's testosterone transdermal gel product in NDA 204399 would contributorily infringe at least one of the claims of the '518 Patent.

129. Upon information and belief, Upsher-Smith had knowledge of the '518 Patent and, by its promotional activities and package insert for its testosterone transdermal gel product in NDA 204399, Upsher-Smith knows or should know that it will actively aid and abet another's infringement of at least one of the claims of the '518 Patent.

130. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith's testosterone transdermal gel product in NDA 204399 would actively induce infringement of at least one of the claims of the '518 Patent.

131. Auxilium and FCB will be substantially and irreparably harmed by Upsher-Smith's infringing activities unless those activities are enjoined by this Court. Auxilium and FCB have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Auxilium and FCB respectfully request that this Court enter judgment in their favor as follows:

(1) A judgment that Defendant has infringed the '968, '605, '606, '607, '608, '609, '610, '690, '029, and '518 Patents under 35 U.S.C. § 271(e)(2)(A);

(2) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of NDA No. 204399 is not earlier than the expiration date of the last-to-expire of the '968, '605, '606, '607, '608, '609, '610, '690, '029, and '518 Patents; or any later expiration of the last-to-expire exclusivity for the '968, '605, '606, '607, '608, '609, '610, '690, '029, or '518 Patent to which Plaintiffs are or become entitled;

(3) A permanent injunction restraining and enjoining Defendant and its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing any product that infringes the '968, '605, '606, '607, '608, '609, '610, '690, '029, or '518 Patent, including the product described in NDA No. 204399;

(4) A judgment declaring that making, using, selling, offering to sell, or importing the product described in NDA No. 204399, or inducing or contributing to such conduct, would

constitute infringement of the ’968, ’605, ’606, ’607, ’608, ’609, ’610, ’690, ’029, and ’518 Patents by Defendant pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

(5) A finding that this is an exceptional case, and an award of attorneys’ fees in this action pursuant to 35 U.S.C. § 285;

(6) Costs and expenses in this action; and

(7) Such further and other relief as this Court determines to be just and proper.

ASHBY & GEDDES

/s/ Steven J. Balick

_____

Steven J. Balick (I.D. #2114)
Lauren E. Maguire (I.D. 4261)
Andrew C. Mayo (I.D. #5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashby-geddes.com
lmaguire@ashby-geddes.com
amayo@ashby-geddes.com

Attorneys for Plaintiffs

Of Counsel:

Paul J. Berman
Keith A. Teel
Uma N. Everett
Erica N. Andersen
COVINGTON & BURLING LLP
1201 Pennsylvania Ave., NW
Washington, D.C. 20004
(202) 662-6000

Dated: January 28, 2013